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TRANSTEK

Section 5 - 510(k) Summary

Date of Summary Preparation: 12/21/2011

1. Submitter's Identifications

Submitter's Name: ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD.
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2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
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3. Name of the Device

Device Classification Name: System, Measurement, Blood-Pressure, Non-invasive
Product Name: TRANSTEK Blood Pressure Monitor
Trade Name: TRANSTEK
Models: LS-802, TMB-1018, TMB-1018-A, TMB-1112, TMB-1112-A
Classification Panel: Cardiovascular
Common/Usual Name: Automatic Blood Pressure Monitor
Product Code: DXN
Device Classification: Class II
Contraindications: Do not use the Analyzer if you have a pacemaker or other internal medical device.

4. The Predicate Devices

TRANSTEK, Blood Pressure Monitor, Model TMB-986, K101681

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5. Device Description

Transtek Blood Pressure Monitor, LS-802, TMB-1018, TMB-1018-A, TMB-1112 and TMB-1112-A are designed to measure the systolic and diastolic blood pressure and heartbeat rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm.

Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating heartbeat rate, which is a well-known technique in the market called the "Oscillometric method".

Transtek Blood Pressure Monitor is single-mounted devices of the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 22 and 42 cm, includes the inflatable bladder and nylon shell. All models of the arm blood pressure monitor can use the same two size of cuff (22 - 32cm, or 22 - 42cm). Product package will contains only one cuff and which size is decide by business requirement. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD. The subject devices are powered by four AAA or AA alkaline batteries or by a DC 6V 400mA adapter.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

6. Intended Use of Device

Transtek Blood Pressure Monitor, Models LS-802, TMB-1018, TMB-1018-A, TMB-1112 and TMB-1112-A are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Blood Pressure Monitor, LS-802, TMB-1018, TMB-1018-A, TMB-1112 and TMB-1112-A models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

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7. Summary of Substantial Equivalence

Table 1: The difference between subjects Transtek Blood Pressure Monitor

Feature	LS-802	TMB-1018	TMB-1018-A	TMB-1112	TMB-1112-A	Comparison
Power supply	Battery powered mode					
	6VDC 4*AA alkaline batteries	6VDC 4*AAA alkaline batteries	6VDC 4*AAA alkaline batteries	6VDC 4*AA alkaline batteries	6VDC 4*AA alkaline batteries	Similar
	AC adaptor powered mode					
	AC 100～240V 50-60 Hz 400mA	AC 100～240V 50-60 Hz 400mA	AC 100～240V 50-60 Hz 400mA	AC 100～240V 50-60 Hz 400mA	AC 100～240V 50-60 Hz 400mA	Similar
Display mode	Digital LCD V.A. 78*92mm	Digital LCD V.A. 140*36mm	Digital LCD V.A. 140*36mm	Digital LCD V.A. 61*93mm	Digital LCD V.A. 41*60mm	Similar
Measurement mode	Oscillographic testing mode	Oscillographic testing mode	Oscillographic testing mode	Oscillographic testing mode	Oscillographic testing mode	Similar
Accuracy	Pressure: 15℃~25℃: within ±3mmHg 10℃~40℃(out of 15℃~25℃): within ±5mmHg Heartbeat: within ±5% of reading	Pressure: 15℃~25℃: within ±3mmHg 10℃~40℃(out of 15℃~25℃): within ±5mmHg Heartbeat: within ±5% of reading	Pressure: 15℃~25℃: within ±3mmHg 10℃~40℃(out of 15℃~25℃): within ±5mmHg Heartbeat: within ±5% of reading	Pressure: 15℃~25℃: within ±3mmHg 10℃~40℃(out of 15℃~25℃): within ±5mmHg Heartbeat: within ±5% of reading	Pressure: 15℃~25℃: within ±3mmHg 10℃~40℃(out of 15℃~25℃): within ±5mmHg Heartbeat: within ±5% of reading	Similar
Measurement range	Pressure: 0～300mmHg Heartbeat: 40～199 Pul/min	Pressure: 0～300mmHg Heartbeat: 40～199 Pul/min	Pressure: 0～300mmHg Heartbeat: 40～199 Pul/min	Pressure: 0～300mmHg Heartbeat: 40～199 Pul/min	Pressure: 0～300mmHg Heartbeat: 40～199 Pul/min	Similar
Measurement perimeter of upper arm	22cm～42cm	22cm～42cm	22cm～42cm	22cm～42cm	22cm～42cm	Similar
Net weight	Approx. 385g	Approx. 300g	Approx. 270g	Approx. 305g	Approx. 305g	Similar
Software	Ver. 1.0	Ver. 1.0	Ver. 1.0	Ver. 1.0	Ver. 1.0	Similar

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Feature	LS-802	TMB-1018	TMB-1018-A	TMB-1112	TMB-1112-A	Comparison
Normal working condition	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Similar
Storage & transportation condition	Temperature: -20~60℃ Relative humidity: ≤90%	Temperature: -20~60℃ Relative humidity: ≤90%	Temperature: -20~60℃ Relative humidity: ≤90%	Temperature: -20~60℃ Relative humidity: ≤90%	Temperature: -20~60℃ Relative humidity: ≤90%	Similar
External dimensions	120*160*69mm	180*100*40mm	180*100*40mm	120*140*70mm	120*140*70mm	Little different
Mode of operation	Continuous operation	Continuous operation	Continuous operation	Continuous operation	Continuous operation	Similar

Table 2: The difference between subject Transtek Blood Pressure Monitor and the predicate device, Transtek Blood Pressure Monitor, TMB-986

Feature	LS-802, TMB-1018, TMB-1018-A, TMB-1112, TMB-1112-A	Predicate: TMB-986	Comparison
Device name	Blood Pressure Monitor	Blood Pressure Monitor	Similar
Indication for use	Measure the blood pressure and heartbeat rate. Irregular heartbeat detection. These models are not intended to be a diagnostic device.	Measure the blood pressure and heartbeat rate. Irregular heartbeat detection. These models are not intended to be a diagnostic device.	Similar
Components	Main Unit, Cuff, Adapter, Instruction Manual, 4*AAA/4*AA batteries, Storage Case and Warranty Card	Main Unit, Cuff, Adapter, Instruction Manual, 4*AAA batteries, Storage Case and Warranty Card	Similar
Energy used	Battery (4*AAA/4*AA) or AC adapter (DC 6V Output)	Battery (4*AAA) or AC adapter (DC 6V Output)	Similar
Display	Liquid crystal digital display	Liquid crystal digital display	Similar
Software	Ver. 1.0	Ver. 1.0	Similar

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Feature	LS-802, TMB-1018, TMB-1018-A, TMB-1112, TMB-1112-A	Predicate: TMB-986	Comparison
External dimensions	LS-802: 120*160*69mm TMB-1018 & TMB-1018-A: 180*100*40mm TMB-1112 & TMB-1112-A: 120*140*70mm	180*100*39mm	Similar
Applicable cuff	Wrap around cuff (Model numbers, 22/32, 22/42)	Wrap around cuff (Model numbers, 22/32, 22/42)	Similar
Accuracy of pressure indicator	Within±3mmHg (15℃~25℃) Within ±5mmHg (10℃~40℃[out of 15℃~25℃])	Within±3mmHg (15℃~25℃) Within ±5mmHg (10℃~40℃[out of 15℃~25℃])	Similar
Accuracy of heartbeat rate	Within ±5% of reading	Within ±5% of reading	Similar
Measurement range	Pressure: 0~300mmHg Heartbeat: 40~199 Pul/min	Pressure: 0~300mmHg Heartbeat: 40~199 Pul/min	Similar
Cuff inflation	Automatic inflation with air pump	Automatic inflation with air pump	Similar
Deflation of pressure	Automatic air release	Automatic air release	Similar
Operating voltage	DC 6V	DC 6V	Similar
Measurement perimeter of upper arm	22cm~42cm	22cm~42cm	Similar
Operating environment	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Temperature: 10℃~40℃ Relative humidity: 15%~90% Barometric pressure: 105~80kPa	Similar
Transport and storage environment	Temperature: -20~60℃ Relative humidity: ≤90%	Temperature: -20~60℃ Relative humidity: ≤90%	Similar

8. Conclusions

The subject devices have all features of the predicate device TMB-986 except display and external dimensions. These differences do not affect the safety and effectiveness of the subject devices. Thus, the subject devices are substantially equivalent to the predicate device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Zhongshan Transtek Electronics Co., Ltd.
c/o Mr. Leo Wang
Consulting Manager
A03 Lab of BTS
No. 1 Fanghua Street
Hi-Tech District
Chengdu, CHINA 610041

Re: K120058
Trade/Device Name: Transtek Blood Pressure Monitor Models: LS-802, TMB-1018, TMB-1018-A, TMB-1112, and TMB-1112-A
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: January 7, 2012
Received: January 9, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 - Indications for Use

510(k) Number (if known):

Device Name:

Transtek Blood Pressure Monitor
Models: LS-802, TMB-1018, TMB-1018-A, TMB-1112, TMB-1112-A

Indications for Use:

This series of devices are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings. The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Blood Pressure Monitor, LS-802, TMB-1018, TMB-1018-A, TMB-1112, and TMB-1112-A models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120058